श्री सभापति: सवाल पूछिए।

श्री राम नारायण साहू: और यहां कोई शिकायत नहीं आती है, लेकिन जब वही डिपार्टमेंट रेलवे के अंदर खाना supply करता है, तो वह खाना सही नहीं होता है।

श्री सभापति: सवाल क्या है?

श्री राम नारायण साहू: सर, यह सभी सदस्यों की शिकायत है। क्या मंत्री जी इस पर ध्यान देंगे?

SHRI K.H. MUNIAPPA: Sir, I have already said that we have taken steps to maintain the quality of food. It depends upon the taste of the people, region-wise. We are supplying food. There is no problem. If the hon. Member has any suggestion, we are ready to take extra steps to improve the things further.

श्री के.वी. शणप्पा: सर, मैं माननीय मंत्री जी से पूछना चाहता हूं कि In the Karnataka Express, which goes from Delhi to Bangalore, there is no First Class facility. But in the Rajdhani Express, there is the facility of First Class. As an MP, when we travel in the First Class, they ask us to write the name of the spouse. When we write it as companion, they do not allow us. हमारी वाइफ नहीं आना चाहती, लेकिन companion allow नहीं है, तो काहे को आप ने यह procedure रखा है?

श्री सभापति : देखिए, यह सवाल दूसरा है। वह आप अलग पूछ सकते हैं।

श्री सभापति: देखिए, यह सवाल दूसरा है ...**(व्यवधान)**...

श्री के.वी. शणप्पा: सर, इस पर answer तो दे सकते हैं। ...**(व्यवधान)**...

श्री सभापति: नहीं, आप इस पर सवाल पूछिए ...**(व्यवधान)**... प्लीज़ ...**(व्यवधान)**...

श्री के.वी. शणप्पा: सर, इस पर भी वह जवाब दे देते। ...**(व्यवधान)**...

श्री सभापति: नहीं-नहीं, यह इससे related नहीं है। ...**(व्यवधान)**... प्लीज़ ...**(व्यवधान)**... श्री वी. हनुमंत राव।

श्री वी. हनुमंत राव: सर, माननीय मंत्री जी ने कहा कि ट्रेनों में क्वालिटी के वास्ते चेक होता है। मैं एक मर्तबा नहीं बल्कि दस मर्तबा ए.पी. एक्सप्रेस और राजधानी एक्सप्रेस से हैदराबाद गया हूँ, लेकिन मैंने एक मर्तबा भी यह नहीं देखा कि उसमें कोई चेक करने वाला भी है। जब अच्छा खाना नहीं मिलता तो हम पैसेंजर्स खुद जाकर इसकी complaint करते हैं।

श्री सभापति: आप सवाल पूछिए।

श्री वी. हनुमंत राव: सर, मैं सवाल यह पूछ रहा हूँ कि मैंने आज तक यह नहीं देखा कि कहीं क्वालिटी कंट्रोल के लिए चैकिंग हुई हो। आप जरा मुझे इसके बारे में बताइए।

SHRI K.H. MUNIAPPA: Mr. Chairman, Sir, if there is any specific complaint, and the hon. Member brings it to my notice, we will correct it.

Closure of vaccine PSUs

*304. SHRI MAHENDRA MOHAN:††
SHRIMATI SHOBHANA BHARTIA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

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††The question was actually asked on the floor of the House by the Shri Mahendra Mohan.

(a) whether Government had suspended the licence of three crucial public sector suppliers of vaccines last year;

(b) if so, whether due to the suspension order on vaccine manufacturing public sector suppliers, the shortage of vaccines has affected Universal Immunization Programme;

(c) if so, the facts thereof;

(d) whether Government has since taken any steps to revive the public sector units to meet the demand of vaccines, particularly for newborns; and

(e) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (e) A statement is laid on the Table of the House.

Statement

(a) Yes. The manufacturing licenses of three Vaccine Institutes namely, the Central Research Institute, Kasauli, Himachal Pradesh, the Pasteur Institute of India, Coonoor, Tamil Nadu and BCG Vaccine Laboratory, Chennai, Tamil Nadu, which are under the administrative control of the Ministry were suspended by the Drugs Controller General of India [DCG(I)] in January, 2008, since they were not found in compliance with the Good Manufacturing Practices (GMP) as provided under Schedule M of Drugs and Cosmetic Rules, 1945.

(b) Yes.

(c) For some months in 2008, there were shortage of Diptheria-Pertussis-Tetanus (DPT), Tetanus Toxoid (TT) and Diptheria Tetnus (DT) in some States due to non-fulfillment of supply commitments by manufacturers. These were overcome by October, 2008, since then there have been no shortage.

(d) and (e) Yes. Government has decided to revive these units. The licenses of these units can be revived and production of vaccines can be restarted after compliance with GMP requirements. The renovation/upgradation of the new building constructed at CRI, Kasauli, to meet GMP norms for manufacture of Diptheria-Pertussis-Tetanus (DPT) group of vaccines is in progress. The project is expected to be completed by June, 2010. The project reports for revival of BCG, Guindy, and PII, Coonoor, are being prepared.

SHRI MAHENDRA MOHAN: Sir, the Government has stated in the reply that these public sector units were not following the Good Manufacturing Practices. Hence these had to be closed down in 2008, as the World Health Organisation threatened action against the National Regulatory Authority. It is surprising that the unit at Kasauli, which was 103 years old, the second unit, which was 100 years old and the third, which was 60 years old, had to be closed down. Since when has it been in the knowledge of the Government that these units were not following the GMP norms? Since they were Government units, it was the responsibility of the Government to see to it that they meet the international quality norms, as India exports vaccines to 151 countries, and 80 per cent of the vaccines were supplied from these units. Why were these old

laboratories not upgraded? And what has been the Drug Controller doing for so many years? What action has been taken against him?

SHRI GHULAM NABI AZAD: Sir, it is very difficult for me to say why the process of upgradation had not started. It should have started long back, but it did not start. That is why, ultimately, the Drug Controller of India was forced to cancel licences of these units, under pressure from the WHO, because they had not fulfilled the Good Manufacturing Practices, which each manufacturing unit was supposed to follow. And, I don't think that for any unit to continue for more than 100 years is possible. There should be a process of upgradation after every 10 or 15 or 20 years. At least, two of these units went by without any upgradation for more than 100 years*...(Interruptions)...* It is not for me to say why it was not done. Out of these 100 years, 40 years were during the pre-independent period*...(Interruptions)...*

SHRIMATI BRINDA KARAT: That is not the issue. The issue is under the Health Ministry, and they cannot ignore it*...(Interruptions)...*

SHRI S.S. AHLUWALIA: If it has not been done, then, it is the Ministry's fault...

श्री सभापति: अहलुवालिया जी, आप जवाब देने दीजिए। ...**(व्यवधान)**...

SHRIMATI BRINDA KARAT: Six months before the WHO team came, they gave a certificate to the Institute at Coonoor that they were doing such good work...

MR. CHAIRMAN: Mrs. Karat, let the Minister reply.

SHRI GHULAM NABI AZAD: Day before yesterday, the hon. Member, Shrimati Brinda Karat, did mention about it while participating in the debate. I think, before going into rigmarole of it, she had said that there is something dangerous in this. Now, I am sure, another supplementary will come from Brindaji. There is something wrong that these vaccine producing units were producing 80-90 per cent of the vaccines in one year, and suddenly, in the next year, the production comes down to zero. And next year, they come to zero. I do not find any reason why a unit, whether in the private sector or public sector, in any part of the world, producing a particular medicine to the tune of 80 per cent of the total requirement in one year, should produce only 10 to 15 per cent in the very next year. There is certainly something wrong there. That is one thing. Whatever you may say, I will never hide anything; be assured of that.

SHRIMATI BRINDA KARAT: Then, Sir, you should have an enquiry.

MR. CHAIRMAN: No, no. Please.

SHRI GHULAM NABI AZAD: The second thing is that there almost seems to be the same nexus, which I have mentioned, so far as equipment in hospitals is concerned. I can smell some nexus between these units and the private units. When that particular unit places orders for vaccines, it is at the normal price, but the next year, there is almost a hundred per cent increase in the price by private vaccine manufacturers. And so these units were paralysed in one year. This needs to be gone into in depth through some external agency. This is what I am going to do.

MR. CHAIRMAN: Second Supplementary.

SHRI MAHENDRA MOHAN: Sir, the Minister has already accepted that there is a nexus. I would like to know why this nexus is not being broken. During the period of closure there was an acute shortage, as stated by the hon. Minister, and, as per the report, the cost of DPT and BCG for the year 2008-09 went as high as Rs. 64.29 crores, whereas it was only Rs. 32 crores earlier. There was a clear nexus because of which supplies were made at a very high price. Later on, when the Central Research Institute at Kasauli...

श्री सभापति: आप सवाल पूछ लीजिए।

SHRI MAHENDRA MOHAN: My question is, renovation has been quoted at only Rs. 15 crores. Why has all this not been taken into account? I think the Minister should place a report on this in the House. My next question is...

MR. CHAIRMAN: You can't have an introductory speech before a question.

SHRI MAHENDRA MOHAN: Okay. My question is very...*(Interruptions)*...

MR. CHAIRMAN: The Minister has given a very...*(Interruptions)*...

SHRI GHULAM NABI AZAD: Well, all this speculation has been put to rest. I have gone deep into the issue and tried to find out how, all of a sudden, within two years' time, these public sector units got paralysed and how the private sector units increased their prices within one year, to the extent of 60, 70 or even 100 per cent. There is something wrong; this can't happen in the normal circumstances.

MR. CHAIRMAN: Fine. The answer has been given.

SHRI MAHENDRA MOHAN: Sir, my second supplementary is...

श्री सभापति: आपने second supplementary पूछ लिया।

SHRI MAHENDRA MOHAN: It should be investigated and a report should be given.

SHRIMATI SHOBHANA BHARTIA: Sir, the problem of immunisation has less to do with availability and more to do with effective implementation, getting mothers to come to ensure that children are vaccinated, for instance. Our track record is poorer than that of even Africa. I would like to know from the hon. Minister if he would consider devising some method to track the entire immunisation programme. I would also like to know whether this new scheme of the Government to have Unique Identity Numbers for every one, would, at some point, converge in helping you track every citizen in this country, including every child, so as to ensure that these vaccines are indeed given to children.

SHRI GHULAM NABI AZAD: Sir, this is what the NRHM, through ASHA, has to do. I would like to say that, in the past, ever since the NRHM came into being, there has been a great relief and a great increase in immunisation; and that will continue. I am sure that with NRHM in place, immunisation will cover, to a great extent, children across the country.

SHRI M. VENKAIAH NAIDU: Mr. Chairman, Sir, when the hon. Member put the question, the hon. Minister is simply saying, 'yes', it will not suffice. The Minister is expected to cause an inquiry and come to the House and then share the information with the House, what has gone wrong and who has done it. Sir, now, my question to the hon. Minister is, will he give an assurance about a time-bound inquiry to find out what has gone wrong, who is responsible, why has the Drug Controller not conducted periodical inspections? There are certain guidelines of the GMP set even by the WHO also. Were those guidelines followed? If not, who is responsible for it? Then, what is the time-limit for the inquiry report? As the Minister himself is saying, and we are all feeling happy, 'ok, fine', because he said that it is being done to help the private sector. It is a fact. I am not disputing what he is saying. When are you going to complete the inquiry, and, then, let the House know about it?

SHRI GHULAM NABI AZAD: Sir, I did not say that it was done to help the private sector. I said, 'there seems to be a possibility of it'. I said so because normally it is not possible for a particular unit that all of a sudden it will stop producing vaccines or medicines.

SHRI M. VENKAIAH NAIDU: All three, Sir.

SHRI GHULAM NABI AZAD: Therefore, I have already said that I will go through it. This question has come only today. I have gone through ...*(Interruptions)*...

SHRIMATI BRINDA KARAT: No, Sir, I raised the entire details and demanded an inquiry into it. ...*(Interruptions)*...

SHRI GHULAM NABI AZAD: Yes, you raised it the day before yesterday. ...*(Interruptions)*... Brindaji, it is not one year or six months or even one month. You raised it the day before yesterday, and I have gone through it yesterday, read it. I can't say anything — it is a huge Ministry — as to what has happened two years back or ten years back, or for that matter, what is happening even today. I can't say what is happening in my Ministry today in any part of the country. It cannot say about it spontaneously, unless it is brought to my notice. And, since it has been brought to my notice, first through your speech, and now through the question, and this is what made me to go deep into this. I myself have come to the conclusion that there is something wrong in it. I have already said that we will have the inquiry done, and as soon as the inquiry is through, I am sure, it is not possible to complete the inquiry within this Session because this Session is hardly of ten days, and also I don't want to come before the House with an inquiry which is half cooked and half baked and not based on the truth. So, as soon as the inquiry is complete, I will come before the House.

SHRI GIREESH KUMAR SANGHI: Sir, the alternate for this is contract manufacturing. If the Government can get these vaccines manufactured on contract basis through private manufacturers, I think that can be a good suggestion. ...*(Interruptions)*... I want to know from the hon. Minister whether he is thinking something on these lines because it will be cost-effective also.

MR. CHAIRMAN: Please put your question. ...*(Interruptions)*...

SHRI GIREESH KUMAR SANGHI: As I said earlier about pool purchase, even contract manufacturing can also be a good suggestion.

SHRI GHULAM NABI AZAD: Sir, I would like to tell the hon. Member that there is no dearth of these vaccines now. The private manufacturers do manufacture it, but the question is of only the cost. After these manufacturing units were closed, the cost of these vaccines has been raised sky-high by the private manufacturers. So, we have to see how this vaccine is made cost-effective, if not close to the cost at which we were producing it, but, at least, somewhere nearly close to that. An increase of hundred per cent should not be done.

SHRI TAPAN KUMAR SEN: Sir, while I appreciate that the Government has decided to revive these units...

MR. CHAIRMAN: Please ask the question quickly because we are running out of time.

SHRI TAPAN KUMAR SEN: Sir, I am just coming to my question. I appreciate that the Government has taken a decision to revive these units, and I also appreciate the point that if the price of these essential vaccines is kept under control, even being produced by the private sector,...*(Interruptions)*...

MR. CHAIRMAN: Mr. Sen, please put your question.

SHRI TAPAN KUMAR SEN: Sir, I am coming to my question. Let me complete the sentence and my question will be complete. The existence of a strong public sector will act as a countervailing weight to keep the price low. My specific question is this. The Kasauli unit project is expected to be completed by 2010. The closure order was done in January, 2008, and the upgradation and completion of the Kasauli unit is expected by 2010. But, why in other two units, at Chennai and Coonoor, it is still at the stage of preparing the project report? This is my specific question. Why these two are neglected?

SHRI GHULAM NABI AZAD: Sir, it is not a one day or one month job. It is not only purchase of just a particular equipment, it also involves new construction. For example, I am talking about Kasauli. Earlier, about 6-7 years back, about Rs. 15 crores was spent on the construction. After that, an inspection took place and it was seen that the construction was not enough to give a completion certificate. Another Rs. 15 crores was given for undertaking more construction. That construction is under progress. It is not just the money that is involved, but also the time is involved for construction, for upgradation, and for equipment. You need money and time, both. That is why, in a phased manner, it is being done. One is under construction, renovation, upgradation; in the meanwhile, the project report of other two is also being prepared.